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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,376	12/31/2003	Keith A. Rindlesbach	01845-22396	4892

20551 7590 11/05/2007

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EXAMINER	
CHOI, FRANK I	
ART UNIT	PAPER NUMBER
1616	

MAIL DATE	DELIVERY MODE
11/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/750,376	RINDLESBACH, KEITH A.	
	Examiner	Art Unit	
	Frank I. Choi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 August 2007, 26 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,11-15 and 17-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,11-15 and 17-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

In view of the Appeal Brief filed on 8/20/2007, PROSECUTION IS HEREBY REOPENED, new grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37.

The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid. A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below.

In light of the above, the Amendment and Declaration filed on 3/26/2007 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 11-15, 17-20 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not

described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are amended to indicate a step (d) for waiting at least 4 hours before administration of indomethacin, adenosyl-L-methionine, selenium and ibuprofen. However, examples 1 and 2 only indicate a 4 hour period and the Specification does not disclose the range of at least 4 hours. See Purdue Pharma L.P. v. Faulding Inc., 230 F.3d 1320, 1328, 56 USPQ2d 1481, 1487 (Fed. Cir. 2000) ("[T]he specification does not clearly disclose to the skilled artisan that the inventors... considered the... ratio to be part of their invention.... There is therefore no force to Purdue's argument that the written description requirement was satisfied because the disclosure revealed a broad invention from which the [later-filed] claims carved out a patentable portion").

Claims 1, 11-15, 17-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. There is insufficient evidence to establish that administration of amoxicillin, vitamin B12, indomethacin, S-adenosyl-L-methionine, selenium, ibuprofen and aspirin will be effective in reducing the effects of Alzheimer's Dementia.

The nature of the invention:

The invention is directed to a method of reducing the effects of Alzheimers Dementia by administering amoxicillin, vitamin B12, indomethacin, S-adenosyl-L-methionine, selenium, ibuprofen and aspirin.

The state of the prior art and the predictability or lack thereof in the art:

The prior art does not appear to disclose or suggest said combination for the treatment of Alzehimer's Dementia. Treatment appears to be limited to providing appropriate levels of stimuli and haloperidol to deal with any anxiety (See Merck Manual (16th Ed. 1992), pp. 1406,1407. Further, as indicated below, patients with severe dementia have been known to become lucid apparently independently of any drug intervention. As such, predictability appears to be low.

The amount of direction or guidance present and the presence or absence of working examples: Although the specification provides information as to doses, working examples are not sufficient to establish that the claimed process is effective in reducing the effects of Alzheimer's Dementia. The working example appears to consist of only a single patient without any controls. However, it is known that patient's with severe dementia, including Alzheimer's patients, can have episodes of lucidity. See Normann et al. (2002), entire document, especially the abstract, Normann et al. (1998), entire document, especially the abstract. The examples set forth in the Specification do not rule out lucid episodes that are not related to drug therapy and do not indicate the duration of the treatment and extent and type of improvement of the dementia. The Examiner has considered the inventor's declaration (3/26/2007), however, the declaration's conclusory statement as to the effect of the treatments set forth in Examples 1 and 2 of the Specification is not supported by any data or records.

The breadth of the claims and the quantity of experimentation needed:

The claims are broad in that they claim a method of reducing the effects of Alzheimer's Dementia where the last step has an open ended time period of at least 4 hours in which to

administerindomethacin, S-adenyosyl-L-methionine, selenium and ibuprofen. As such, in light of the above, one of ordinary skill in the art would be required to do undue experimentation in order to determine at what dosing intervals, order of dosing, etc. of the same would be effective in reducing the effects of Alzheimer's dementia.

The Examiner has duly considered the Applicant's arguments but deems them unpersuasive.

The Applicant has provided evidence that the examples are not prophetic in nature. However, as indicated above, the declaration does not provide sufficient evidence to show that the method as claimed is effective in reducing the effects of Alzheimer's Dementia in a patient. The Applicant provides no evidence that the experimentation is the type typically engaged by those skilled in the art or skilled in the art most closely associated with the invention. See In re Knowlton, 183 USPQ 33,37 (C.C.P.A. 1974)(where the record consisted substantially of arguments and opinions of applicant's attorney, the court indicated that factual affidavits could have provided important evidence on the issue of enablement). Since patients with dementia can become lucid, the testing of a single patient is insufficient to establish that the claimed methods would be effective reducing the effects of Alzheimer's Dementia. The claimed method does merely require determining doses, dosing intervals, order of dosing, etc., the claimed method also requires that the same be effective in reducing the effects of Alzheimer's Dementia. Since there is insufficient support in the Specification to establish that the claimed method is what resulted in said reduction, undue experimentation would be required.

Conclusion

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a compressed schedule and may be reached Monday, Tuesday, Thursday, Friday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Johann R. Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi
Patent Examiner
Technology Center 1600
October 30, 2007

Johann R. Richter
Supervisory Patent Examiner
Technology Center 1600